

### **REMARKS**

The Office Action mailed October 24, 2003 has been received and the Examiner's comments carefully reviewed. Claims 1, 5-7, 10-11, 14-15, 21, 26-28, and 30 have been amended. Claims 31-32 have been added. No new subject matter has been added. Claims 9 and 29 have been cancelled. Claims 1-8, 10-28 and 30-32 are currently pending. For at least the following reasons, Applicant respectfully submits that the pending claims are in condition for allowance.

It is noted that Applicant submitted a Supplemental Information Disclosure Statement on January 8, 2003. Applicant respectfully reminds the Examiner to return a copy of the initialed 1449 Form after the Examiner has had an opportunity to review the submitted references.

In addition, it appears one reference under "Other Documents" was inadvertently not initialed on another 1449 Form dated October 12, 2001. Applicant asks that the Examiner kindly return another copy of the completed Form 1449 dated October 12, 2001.

### **Rejections Under 35 U.S.C. §112**

The Examiner rejected claim 21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which the applicant regards as the invention. In particular, the Examiner states that the term "the device" is unclear. Applicant has amended claim 21 to clarify that "the device" refers to the simulated endoscope device. Applicant respectfully requests withdrawal of this rejection.

### **Rejections Under 35 U.S.C. §102**

The Examiner rejected claims 1-8, 11-21, and 24-30 under 35 U.S.C. §102(b) as being anticipated by Malchesky (U.S. Patent 5,928,948). Applicant respectfully traverses this rejection, but has amended claims 1, 5-7, 11, 14-15, 21, 26-28, and 30 to advance this application to allowance. Applicant reserves the right to pursue the original subject matter via a continuation application.

Malchesky discloses a method for the assessment of a cleaning process. The method includes providing a porous material contaminated with soil, cleaning the porous material, and analyzing the residual soil on the porous material. The soil may be one of a number of

composite standard, or "synthetic," soils. Alternatively, samples of protein or other biological materials may be used, including blood, mucous, . . . . Column 3, lines 19-25.

I. Claims 1-8

Claim 1 recites a method for assessing and evaluating a cleaning process including providing biofilm matrices on a support, subjecting the support and biofilm matrices to the cleaning process, and evaluating the cleaning process by analyzing the presence of remaining biofilm matrices.

Malchesky does not disclose a method of analyzing biofilm or biofilm matrices. Rather, Malchesky discloses only a method for analyzing residual soil. Biofilm is not "soil", as defined in Malchesky. In contrast, biofilm is produced by microorganisms. Specification, page 10 at lines 3-4. In particular, biofilm is a formation of polysaccharide matrices that form when the microorganisms excrete a slimy, glue-like substance. Page 4 at lines 13-15.

Claims 1 and 5-7 have been amended to clarify that the method includes analyzing biofilm matrices, not soil. By detecting and analyzing biofilm matrices rather than soil, a more realistic picture of medical device contamination can be analyzed. In a medical device environment, the optimal conditions of temperature, moisture and nutrients can be present such that a microorganism can and often does grow into a biofilm colony. The biofilm colony has been shown to be a structured extracellular matrix wherein many microorganisms can be protected and grow even when subjected to traditional cleaning and disinfecting methods. The microorganisms within the extracellular matrices can be rendered inactive, but the structured extracellular matrix still can exist for future microbial contaminations. As such, the biofilm matrices are not the traditional proteins or soils used to evaluate cleaning, as disclosed in Malchesky. Rather, detection of biofilm matrices presents a different and more challenging problem that is addressed by the present application. In particular, a Malchesky device may, for example, determine that no soil is present on a support, however biofilm contamination may still remain undetected.

The implications of biofilm contamination in medical devices has only been fully recognized in recent times and methods used to detect traditional microorganisms and non-biofilm structures do not address challenges presented by biofilm structures or matrices. As stated in the specification, on page 5 at lines 1-7, Malchesky ignores the problem of biofilm

formation. Malchesky rather analyzes residual soil. Malchesky does not disclose the analysis of the formation of polysaccharide matrices (i.e. biofilm) produced by microorganisms that may grow on residual soil.

At least because Malchesky fails to disclose a method involving the analysis of biofilm matrices, Applicant respectfully submits that independent claim 1, and dependent claims 2-8 are patentable.

## II. Claims 11-13

Claim 11 recites a method for accessing and evaluating a cleaning process including contaminating a support with a known biofilm, the biofilm including biofilm matrices. The method also includes subjecting the support and biofilm matrices to the cleaning process and evaluating the cleaning process by evaluating the support for remaining biofilm matrices.

At least for similar reasons as discussed with regards to claim 1, Applicant respectfully submits that independent claim 11, and dependent claims 12-13 are patentable.

## III. Claim 14

Claim 14 recites a cleaning system including a simulated endoscope having a biofilm coating including biofilm matrices and a biofilm-specific indicator. The system also includes a light source to detect the biofilm-specific indicator. The biofilm-specific indicator specifically binds to the biofilm matrices of the biofilm coating.

Malchesky does not disclose a system that includes a biofilm coating and a biofilm-specific indicator. Rather, Malchesky discloses a system that discloses a system having a porous material 10 that is contaminated with soil 14. Accordingly, Malchesky discloses an infrared light source 44 and photo detector 46 that produce an output indicative of a percentage of residual soil. Columns 4-5, lines 60-30. "Soil", as defined in Malchesky, is not a biofilm coating having biofilm matrices, and the soil detector is not a biofilm-specific detector that binds to biofilm matrices of the biofilm coating. At least for these reasons, Applicant respectfully submits that independent claim 14 is patentable.

IV. Claims 15-21 and 24-26

Claim 15 recites a simulated endoscope device including a biofilm coating including biofilm matrices and a biofilm-specific indicator. Claim 26 recites an endoscope cleaning assembly having a biofilm coating including biofilm matrices and a biofilm-specific indicator. At least for similar reasons as discussed with regards to claim 14, Applicant respectfully submits that independent claims 15 and 26, and dependent claims 16-21 and 24-25, are patentable.

V. Claim 27

Claim 27 recites a method of cleaning an endoscope including the step of attaching a simulated endoscope device to an endoscope cleaning device, the simulated endoscope device including a biofilm coating with biofilm matrices and a biofilm-specific indicator. The method further includes determining the presence or absence of biofilm matrices after the cleaning cycles. At least for similar reasons as discussed with regards to claim 1 and claim 14, Applicant respectfully submits that claim 27 is patentable.

VI. Claims 28 and 30

Claim 28 recites a method for assessing and evaluating a cleaning process, the method including the steps of providing a simulated instrument contaminated with biofilm matrices, subjecting the simulated contaminated instrument to the cleaning process, and evaluating the cleaning process by analyzing the simulated instrument for the presence of remaining biofilm matrices.

At least for similar reasons as discussed with regards to claim 1, Applicant respectfully submits that independent claim 28 and dependent claim 30 are patentable.

**Rejections Under 35 U.S.C. §103**

The Examiner rejected claims 9-10 and 22-23 under 35 U.S.C. §103(a) as being unpatentable over Malchesky (U.S. Patent 5,928,948). Applicant respectfully traverses this rejection, however, Applicant has cancelled claim 9 to advance this case to allowance.

VII. Claim 10

Claim 10 depends upon claim 1. In view of the remarks regarding independent claims 1, further discussion regarding the independent patentability of dependent claim 10 is believed to be unnecessary. Applicant submits that dependent claim 10 is in condition for allowance.

VIII. Claims 22-23

Claims 22-23 depend upon claim 15. In view of the remarks regarding independent claims 15, further discussion regarding the independent patentability of dependent claims 22-23 is believed to be unnecessary.

Nonetheless, Applicant notes that claim 22 recites that the biofilm-specific indicator is provided in a frangible chamber. Malchesky does not disclose a frangible chamber. Applicant respectfully disagrees that placing a biofilm indicator within a frangible chamber, and further placing the frangible chamber within the length of tubing (as recited in claim 23) is obvious, as asserted by the Examiner. On the contrary, none of the art teaches or suggests a device having the arrangement as recited. At least for this reason, Applicant submits that rejection of claims 22-23 is improper and respectfully requests withdrawal of this rejection.

**New Claims 31-32**

New claims 31-32 depend upon claim 1. Claims 31-32 recite a method including introducing a biofilm indicator to the support wherein the biofilm indicator binds to extracellular portions of the biofilm matrices. None of the cited art discloses a biofilm indicator that binds to extracellular portions of the biofilm matrices.

Claim 32 recites a method including breaking a frangible vial position inside an interior of the support to expose any remaining biofilm matrices to a biofilm indicator contained within the frangible vial. None of the cited art discloses a frangible vial containing a biofilm indicator or breaking such a vial to expose the biofilm matrices to a biofilm indicator.

At least for these reasons, Applicant respectfully submits that claims 31-32 are patentable.

### SUMMARY

It is respectfully submitted that each of the presently pending claims (claims 1-8, 10-28 and 30-32) is in condition for allowance and notification to that effect is requested. The Examiner is invited to contact Applicant's representative at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

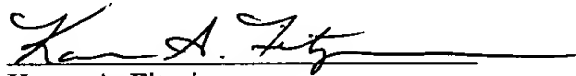
Although certain arguments regarding patentability are set forth herein, there may be other arguments and reasons why the claimed invention is patentably distinct. Applicant reserves the right to raise these arguments in the future.

Respectfully submitted,

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